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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/319,831	10/06/1994	RODNEY M. HEWICK	GI5182ADIV	9112

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/319,831	Applicant(s) HEWICK ET AL.	
	Examiner Elizabeth C. Kemmerer, Ph.D.	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The suspension of prosecution is hereby terminated. Prosecution is re-opened.

Upon further consideration, the indication of record that all claims are allowable is *withdrawn* in view of the re-instated grounds of rejection, below.

Claims 2-25 and 30 are canceled. Claims 1 and 26-29 are under examination.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1646, Examiner Elizabeth C. Kemmerer, Ph.D.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 26-29 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,266,683 (Oppermann et al.; of record).

The instant application is accorded benefit of the filing date of priority document PCT/US91/03388 (15 May 1991), as well as parent U.S. Patent Application Serial Number 07/800,364 (filed 26 November 1991). Applicant also claims priority to U.S. Patent Application Serial Numbers 07/525,357 (filed 16 May 1990) and 07/641,204

(filed 15 January 1991). Priority is not granted to '204 since there is inadequate written description and enablement support for the protein recited in the instant claims. The protein recited in the instant claims must comprise three partial sequences. These sequences can be found in human BMP-8. '204 only discloses a partial sequence for a bovine BMP-8 and does not disclose any of the three partial sequences recited in the instant claims. Although the specification of '204 provides a method by which the human BMP-8 protein could be isolated, no proteins are disclosed which comprise the three partial sequences recited in the instant claims. Therefore, the specification of '204 is not enabling, and fails to provide adequate written description, for the instantly claimed protein and pharmaceutical compositions. Unfortunately, the '357 application has been lost by the USPTO. The inconvenience and cost to Applicant are truly regretted. Applicant may wish to reconstruct this file for USPTO records and is invited to contact the examiner to arrange such. However, since the claimed protein was not enabled or adequately described in the '204 application at the filing date of 15 January 1991, it is reasonable to assume that such a protein was not disclosed in the earlier application ('357) filed 16 May 1990.

'683 teaches a purified BMP-8 protein (named hOP2 by '683). See claim 26. The protein taught by '683 comprises all three sequences recited in instant claim 1. See SEQ ID NO: 28 of '683, wherein SEQ ID NO: 1 recited in part i) of instant claim 1 is shown at residues 303-325 of '683 SEQ ID NO: 28; SEQ ID NO: 2 recited in part ii) of instant claim 1 is shown at residues 372-389 of '683 SEQ ID NO: 28; and SEQ ID NO: 3 recited in part iii) of instant claim 1 is shown at residues 365-371 of '683 SEQ ID NO:

Art Unit: 1646

28). It is noted that '683 has an effective filing date of 18 October 1990, the filing date of parent application 07/599,543, which first discloses hOP2, SEQ ID NO: 28.

'683 also teaches a pharmaceutical composition comprising hOP2 and a pharmaceutically acceptable vehicle (called a "device" in '683; column 5, lines 8-23; col. 10, lines 45-63). The device has bone formation activity, useful for repair of bone tissue (relevant to claims 26 and 29). The device taught by '683 comprises a matrix for supporting the pharmaceutical composition and providing a surface for bone formation (col. 5, lines 8-23; paragraph bridging columns 11-12). Finally, the matrix taught by '683 comprises hydroxyapatite or tricalcium phosphate (paragraph bridging columns 11-12).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

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